UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: COLUMBIA UNIVERSITY PATENT LITIGATION	**MDL NO. 1592**
IMMUNEX CORPORATION, a Washington Corporation and AMGEN INC., a Delaware Corporation, **Plaintiffs,** **vs.** **THE TRUSTEES OF COLUMBIA UNIVERSITY in the City of New York, a New York Corporation,** **Defendant**	**CIVIL ACTION NO.: 04-10740-MLW** **C. D. Cal. No. CV 03-4349 (CWx)** **Judge Mark L. Wolf**
AND RELATED COUNTERCLAIM.	

MEMORANDUM OF PLAINTIFFS AMGEN INC. AND IMMUNEX CORPORATION IN RESPONSE TO THE COURT'S ORDER OF MAY 17, 2005

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Amgen Inc. and Immunex Corporation (collectively "Amgen") file this memorandum in response to the Court's May 17 Order, directing the parties to address certain issues. The four of those issues that pertain to Amgen are "(a)" whether Amgen's first and seventh claims survive the Court's November 5, 2004 Order because they allege that Columbia is seeking royalties on the basis of the original Axel patents, "(e)" whether Amgen should be granted leave to amend its complaint; "(f)" whether Amgen should be allowed to consolidate the new complaint by its affiliates with whatever portion of the MDL cases survives the November 5 Order and "(g)" whether, if part of Amgen's case remains, it should be remanded. This memorandum addresses those four issues in order.[1]

Having spent considerable time and effort consolidating the various actions relating to Axel patents, Columbia now is attempting to remove as many of these actions as possible from this Court. Regardless of the Court's ruling on the pending motions to amend, to consolidate or to dismiss, Columbia's motion for suggestion of remand lacks merit. Amgen requests the Court to proceed with pretrial proceedings of the remaining cases in this MDL, which cases concern overlap of facts and issues. These facts require analysis of the subject matter of the Axel patents, and of Columbia's pattern of egregious conduct designed to obtain, extend and enforce those patents, including its inequitable conduct before the U.S. Patent and Trademark Office ("PTO"). Columbia obtained the consolidation of these actions in this Court by extensively portraying the common facts and witnesses, and advocating judicial economy. That same judicial economy remains and is even more compelling now in light of this Court's familiarity with these issues.

[1] The Court's May 17, 2005 Order also directed the parties to confer regarding narrowing the issues in dispute and determining whether their cases could be settled. In compliance with that direction, in-house counsel of Amgen and Columbia met at Columbia to discuss settlement, and progress was made and discussions are ongoing**.** Amgen and Columbia outside counsel conferred regarding narrowing of the issues. No narrowing of issues was achieved.

I. AMGEN'S FIRST AND SEVENTH CLAIMS SURVIVE THE NOVEMBER 5, 2004 ORDER

Amgen filed its Second Amended Complaint ("SAC") in December, 2003. At that time, it sought several items of relief that the Court has held are mooted by Columbia's Covenant not to Sue (the "Covenant"). Two of Amgen's claims are not moot:

- Amgen's request for a declaration that no royalties are due to Columbia under the parties' license agreement (First Claim for Relief); and
- Amgen's request for a declaration that Columbia's misconduct in connection with the events leading to and concerning the Axel patents constituted "repressive practices" in breach of the license agreement (Seventh Claim for Relief).

As explained in Section II below, Amgen's Third Claim, if amended, also survives the Motion to Dismiss.

The First Claim Survives: Amgen does not owe Columbia any more royalties, and accordingly pleaded a First Claim for Relief entitled "Declaratory Judgment that Amgen and Immunex Owe *No* Royalties." SAC at 18 (emphasis added). An actual controversy exists because Columbia seeks royalties "for sales of Licensed Products by Amgen in the period from August 16, 2000 to date." Letter, White to Odre, Dec. 28, 2001, copy attached as Exhibit 1. Columbia's demand was not limited to product sold by August 16, 2000 (when the first three Axel patents expired). Instead, Columbia explained that it wanted royalty on sales after that date, whether the product was already made ("vialed") by that date, or merely "in-process" by that date or entirely made after that date. *Id.* One – but only one – of the rationales offered by Columbia was that "in-process" product and product entirely made after that date were covered by the pendency of applications, one of which became the '275 Patent. *Id.*

Columbia's contention that the claims do not survive the Motion to Dismiss depends upon its narrow misreading of the claim. Amgen's pleading was not limited to that part of Columbia's royalty claims that concerned product made after August 16, 2000. Although Amgen mentioned in

the SAC Columbia's rationale that Amgen should pay royalties because of pending patent applications – a theory so egregious it has since been abandoned by Columbia – Amgen expressly referenced this only as an "*inter alia*" example of Columbia's rationales. Columbia has not abandoned its other rationales. Amgen's request for a declaration that *no* royalties are owed is as broad as Columbia's counterclaims for royalties. Amgen's First Claim broadly alleges that no royalties are owed just as Columbia's counterclaims so allege. Unsurprisingly, Columbia agreed that its counterclaims survive the Motion to Dismiss and does not offer such a constrained reading for them.

The Seventh Claim Survives: The United States funded the research at Columbia that led to the filing of the Axel patent applications. Accordingly, when the United States (through the Department of Health and Human Services ("HHS")) agreed to assign the patent rights to Columbia, it did so only subject to a series of conditions, one of which is that Columbia refrain from "unreasonable royalties" and "repressive practices."[2] This prohibition was broadly intended to enforce the public interest applicable to Columbia having title to a publicly-funded invention. As part of implementation of this condition, it was made contractually enforceable by Amgen through Amgen's license.[3]

The Seventh Claim incorporates by reference the alleged misconduct of Columbia, and pleads that this misconduct constituted "repressive practices" within the meaning of the license agreement, thus constituting a failure of performance of a condition of the agreement by Columbia.

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[2] The obligation to refrain from "unreasonable royalties" and "repressive practices" (collectively referenced here as "repressive practices") was stated in the HHS letter assigning rights to Columbia which was incorporated by reference into Amgen's license agreement with Columbia. *See* Exhibit 2 hereto, consisting of the license agreement and its Appendix A (the HHS letter), condition (j).

[3] In two motions to dismiss aimed at this claim for relief, Columbia never argued that this condition was not enforceable by licensees, but Columbia has recently raised this afterthought argument in briefing directed at Biogen. However, the HHS grant letter to Columbia specifically required Columbia to incorporate this and other conditions applicable to Columbia into all licenses, and the parties made the letter a part of the Amgen license.

As a result "Amgen and Immunex Have *No* Contractual Royalty Obligations," and Amgen sought a declaration that its "obligation to pay additional royalties is excused." SAC at 23 and ¶ 91 (emphasis added). The relief sought was *not* limited to only some of the royalties claimed by Columbia.

Columbia's Covenant regarding the '275 patent does not obviate Columbia's brandishing of that patent inconsistent with its obligations under the license, or Columbia's misconduct over the years in the prosecution of the Axel patents. As Amgen explained in successful opposition to Columbia's motion to dismiss this claim in the transferor court, "Columbia's repressive practices occurred over a period commencing in the 1980's, including conduct well before Amgen ceased paying royalties." Memo. of Pts. and Auths., filed Jan. 12, 2004, Appendix A hereto, at 9, n. 6.[4] These allegations are not limited to obtaining and enforcing the '275 patent.

II. LEAVE TO AMEND SHOULD BE GRANTED

Since the time Amgen filed the SAC, several relevant events have occurred and facts come to light, closely tied to the transactions and occurrences alleged in the SAC. To avoid unnecessary multiplication of litigation, Amgen moved to amend to reflect those changes, which principally relate to:

- Certain revelations, during recent Court-ordered discovery of witnesses to preserve testimony and through related investigation, showing that Columbia committed additional misconduct in procuring the prior expired Axel patents.[5]

[4] Copies of certain memoranda and pleadings as previously filed are submitted herewith for convenience in separate Appendixes.

[5] This matter is already placed at issue as a defense in Amgen's Reply to Defendant Columbia's Counterclaims For Breach Of Contract And Declaratory Relief (*see* Fifth Defense), but in light of additional discovery should also be added to the Complaint. The new material is found in paragraphs 30-44 of the proposed Third Amended Complaint ("TAC"), attached hereto as Exhibit 3 A redline of the TAC against the SAC is attached as Exhibit 4. The facts alleged in section E(ii) through (vii) of the TAC are reordered but are found, respectively, in sections E(v), (vi) and (i) through (iv) of the SAC.

- The revelation on September 22, 2004, that Columbia granted at least one other licensee, Genetics Institute, a more favorable royalty rate, entitling Amgen to relief under the "most favored licensee" royalty provision of its license, and discovery of overpayments by Immunex Corporation to Columbia under its license;[6]
- Columbia's purported termination of its license agreement with Amgen on March 9, 2004, reaffirmed September 13, 2004;[7]
- A continued pattern of misconduct by Columbia – including in this litigation – that forms further evidence of its "repressive practices," which are relevant to Columbia's performance under its license agreement with Amgen.[8]

Some of these facts had not yet occurred when the SAC was filed, including Columbia's purported termination of the Amgen license agreement and Columbia's filing of a reissue application to broaden the '275 patent claims after 23 years of prosecution.

The other proposed amendments reflect facts that have only recently come to light. Amgen learned of Genetics Institute's sweetheart deal when Genetics Institute filed its license in this action on September 22, 2004. Columbia's misconduct in failing to disclose material information during prosecution of the prior expired Axel patents also came to light recently. For example, pursuant to the Court's Orders for preservation of testimony, Amgen established at the deposition of Dr. Sol Goodgal on October 18 and 19, 2004 the facts, *inter alia*, that (1) at least by February 25, 1980, Dr. Goodgal carried out cotransformation of CHO cells with the gene for ouabain resistance and the

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[6] These matters are already placed at issue as a defense in Amgen's Reply to Defendant Columbia's Counterclaims For Breach Of Contract And Declaratory Relief (*see* denials of paragraphs 14-16, 18-20, and Sixteenth Defense), but in light of additional discovery should also be added to the Complaint for affirmative relief (*see* TAC at ¶¶ 78-80).

[7] *See* TAC at ¶¶ 74-75.

[8] This matter is already placed at issue as a defense in Amgen's Reply to Defendant Columbia's Counterclaims For Breach Of Contract And Declaratory Relief (*see* Twelfth Defense), but in light of additional discovery should also be added to the Complaint (*see* TAC at ¶ 75).

gene conferring the ability to survive in the absence of the amino acid proline, and (2) in October 1979, Dr. Goodgal discussed with Michael Wigler, one of the Axel patent's named inventors, his work on CHO cell transformation using the ouabain resistance gene. *See* TAC at ¶¶ 34-36, 38-39.[9]

The proposed amendments relate to issues that are not mooted by this Court's ruling on Columbia's motion to dismiss. Columbia's additional misconduct, *e.g.*, in procuring the prior expired Axel patents, is further evidence of Columbia's repressive practices (Seventh Claim for Relief, and also a defense to Columbia's Counterclaims), and provides inequitable conduct and unclean hands defenses to Columbia's ongoing claims for additional royalty (like that pleaded now in the Third Claim for Relief with regard to the '275 patent). Columbia's failure to inform Amgen of the more favorable royalty rate to Genetics Institute, and facts showing overpayment by Immunex, are directly relevant to Amgen's claim that no further royalty under the prior expired Axel patents is owed and indeed support affirmative contractual recovery of the overpayments. Columbia's purported termination of the license agreement based on non-payment of contested amounts was wrongful and should be declared ineffective as requested in Amgen's First Claim.

Columbia presented no justification for refusing amendment to add these newly discovered facts. Although amendment of pleadings is largely a matter within the discretion of the district court, Rule 15(a) provides that "leave shall be freely given when justice so requires." *Farkas v. Texas Instruments, Inc.*, 429 F.2d 849, 851 (1st Cir. 1970), *cert. denied*, 401 U.S. 974 (1971); s*ee also One Beacon Ins. Co. v. Electrolux*, 223 F.R.D. 21, 24 (D. Mass. 2004) ("Leave to amend

[9] Similarly, the Court's orders for preservation of testimony allowed Amgen to establish at the deposition of Dr. P. R. Srinivasan on September 14, 2004 and the deposition of Dr. Louis Siminovitch on November 16, 2004, *inter alia*, that (1) while Dr. Srinivasan was on sabbatical from Columbia University from September 1977 to September 1978, he and Dr. William H. Lewis worked in Dr. Siminovitch's laboratory, and successfully transformed CHO cells; and (2) Dr. Srinivasan informed Richard Axel in a July 1978 letter about this work on CHO cell transformation using several markers including a mutant dhfr gene. *See* TAC at ¶¶ 32-33, 40. Investigation of these matters led Amgen to discover additional misconduct of Columbia in failure to disclose material information during prosecution of the prior expired Axel patents. *See* TAC at ¶¶ 42-43.

under Rule 15 'is freely given when justice so requires' absent an adequate basis to deny amendment such as futility, bad faith, undue delay or a dilatory motive").

This is especially true where, as here, the case is still in the pretrial stage and discovery has not begun:

> [D]elay itself will not serve as a basis for denying . . . [the] motion unless the defendant is prejudiced . . . . Moreover, such prejudice ordinarily is not considered to have occurred unless the motion is made during or after the actual trial . . . . Since the defendants have completed only initial discovery, they should be able to prepare their defense to these new claims.

New Balance Athletic Shoe, Inc. v. Puma USA, Inc., 118 F.R.D. 17, 20-21 (D. Mass. 1987) (internal citations and quotations omitted).

Even where discovery is complete, "[a]mendments should be granted unless the court finds an inordinate measure of undue delay, dilatory motive, futility, or undue prejudice." *Martin v. Sands*, 62 F. Supp. 2d 196, 198 (D. Mass. 1999) (permitting defendants to amend answer despite completion of discovery and delay of seventeen months between filing of answer and the motion to amend). Amgen's proposed amendments were indisputably brought to the attention of the Court without undue delay and without dilatory motive since the proposed amendments are based upon new events and newly-discovered information. *Kas v. Fin. Gen. Bankshares, Inc.*, 105 F.R.D. 453 (D.D.C. 1985) (granting motion to amend complaint to include new facts discovered as a result of the completion of discovery and finding no undue delay, bad faith or dilatory motive where the "new facts were not known earlier by the plaintiffs and thus could not have been included in the complaint or first amended complaint; and that as soon as these facts came to light, plaintiffs promptly sought to bring these facts to the attention of the Court by filing the instant motion").

Amgen's amendments similarly are not futile.

> "Futility" means that the complaint, as amended, would fail to state a claim upon which relief could be granted. In reviewing for "futility," the district court applies the same standard of legal sufficiency as applies to a Rule 12(b)(6) motion.

Glassman v. Computervision Corp., 90 F.3d 617, 623 (1st Cir. 1996). Amgen's amendments do not fail to state a claim upon which relief may be granted. As to the First Claim, Amgen merely seeks to add additional facts. Apart from Columbia's argument that the First Claim is mooted by the Covenant, Columbia does not deny this states a proper claim. As to the Seventh Claim, Amgen also merely seeks to add additional facts to support a claim which Columbia has unsuccessfully moved to dismiss.

Amgen seeks to amend its previous Third Claim which, though mooted as to the '275 patent by this Court's November 5 Order, should be directed at the prior expired Axel patents to add recently discovered inequitable conduct facts, which are pled with particularity and are not vulnerable to a motion to dismiss for failure to state a claim. Columbia contends that Amgen would still owe royalties for licensed activity before it gave notice to Columbia that it was going to challenge a prior issued Axel patent, citing *Studiengesellschaft Kohle v. Shell Oil Co.*, 112 F.3d 1561 (Fed. Cir. 1997). Columbia Br. in Opp. to Amgen's Mot. to Amend and Supplement Compl., Dec. 22, 2004, at 7, n.3. But that case concerned an innocent licensor of an *invalid* patent, not a culpable licensor who engaged in inequitable conduct before the PTO to obtain a patent that is *unenforceable*. Indeed, one will search *Studiengesellschaft Kohle* in vain for <u>any</u> express reference to the unenforceability of a patent, let alone a suggestion that *Studiengesellschaft Kohle's* holding should be extended to unenforceable patents. The *Studiengesellschaft Kohle* notice requirement should not be extended to unenforceability because the equities favor the licensee due to the culpability of the patentee who obtains an unenforceable patent by engaging in inequitable conduct. In such circumstances, the general rule should be followed, that a licensee should not be required to pay royalties under an unenforceable patent. *See Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969).

Finally, the proposed amendments would not unduly prejudice Columbia. The amendments are sought before discovery has begun (other than very limited discovery obtained by special order of the Court). And, contrary to Columbia's arguments in the Joint Report, the amendments are not

being introduced after Amgen's action has been dismissed. The amendments are to add facts pertinent to issues that do not depend on further enforcement of the '275 patent and therefore that have not been dismissed as a result of Columbia's Covenant. Columbia's argument against a proposed supplementation of Biogen's complaint – that a court should not grant leave to amend after a case has been resolved – is very different from the situation where, as here, there is no final judgment on the merits of outstanding claims that admittedly remain before the Court. *Stewart v. Angelone*, 186 F.R.D. 342, 343 (E.D. Va. 1999).

In this case the policy of liberal amendment is reinforced by the policy favoring punishing Columbia's misconduct at the PTO. *Key Pharm., Inc. v. Lower*, 373 F. Supp. 1190, 1193 (S.D.N.Y. 1974). In *Key Pharmaceuticals*, plaintiff-licensee sued defendant-licensor seeking rescission of the original agreement due to fraud in its inducement and violations of the Sherman Act. After discovery, the plaintiff-licensee moved to amend its complaint in order to add additional facts concerning the antitrust allegations and to delete the fraud claims. The defendant-licensor opposed, arguing that the amendment would radically alter the legal theory and factual basis of the case and would require extensive additional discovery. However, the court granted the motion to amend, recognizing the general principle that leave to amend should be freely given *(id.* at 1193) and further stating that a court:

> should be particularly lenient in allowing amendment of the pleadings to raise issues of patent misuse and consequent unenforceability since "the possession and assertion of patent rights are 'issues of great moment to the public'." *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 815, 89 L. Ed. 1381, 65 S. Ct. 993 (1945), quoting from *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 246, 88 L. Ed. 1250, 64 S. Ct. 997 (1944). The implementation of this public policy is not "at the mercy of the parties," but the Court should, even *sua sponte,* refuse to enforce patents which have been misused by attempting to extend the patent monopoly. *Vitamin Technologists v. Wisconsin Alumni Research Foundation,* 146 F.2d 941, 944-945 (9th Cir. 1944).

Id. at 1193-94. Thus, Amgen's motion to amend is especially proper to present recently-uncovered facts relating to Columbia's misconduct in prosecution leading to all of the Axel patents.[10]

III. AMGEN SHOULD BE ALLOWED TO CONSOLIDATE THE NEW COMPLAINT BY ITS AFFILIATES WITH WHATEVER PORTION OF THE MDL CASES SURVIVES THE NOVEMBER 5 ORDER

Efficiency dictates that this action be consolidated with *Amgen Mfg., Ltd., Immunex Rhode Island Corp., and Amgen USA, Inc. v. Trustees of Columbia University*, Action No. 04-12626 MLW. That action (hereafter the "Amgen Affiliates action") was filed by certain affiliates of Amgen to raise, on their own behalf, issues based upon the same facts and issues that were raised and are raised by Amgen and other plaintiffs in this MDL proceeding. Although some of the legal theories presented in this MDL proceeding have been mooted by Columbia's Covenant, that Covenant does not extend to the Amgen Affiliates, and the facts still at issue in this MDL proceeding (*e.g.*, under contract theories and defenses) substantially overlap with the facts at issue in the Amgen Affiliates action.

In determining whether to order consolidation, a court must first ask whether the two proceedings involve a common party and common issues of fact or law. *Seguro de Servicio de Salud de Puerto Rico v. McAuto Sys. Group, Inc.*, 878 F.2d 5, 8 (1st Cir. 1989). Once that determination has been made, the court has "broad discretion in weighing the costs and benefits of consolidation to decide whether that procedure is appropriate." *Id.* If the threshold questions are resolved in favor of consolidation, it will usually be allowed unless the opposing party can demonstrate prejudice. *Cf. Procter & Gamble Co. v. Nabisco Brands, Inc.*, 604 F. Supp. 1485, 1493 (D. Del. 1985) (plaintiff patentee's motion granted to consolidate for trial three infringement actions it filed against different defendants).

[10] For further discussion of the reasons supporting Amgen's Motion to Amend, please see its opening and reply memoranda on that motion, submitted herewith as Appendices B and C.

These requirements are satisfied here. Columbia is the common defendant in the actions sought to be consolidated. And the overlapping issues of fact are numerous. For example, the pattern of misconduct of Columbia before the PTO regarding all of the Axel patents (*e.g.*, its failure to disclose material information by the inventors before the first Axel patent was issued – *see* SAC at ¶ 50) is relevant both to the Amgen Affiliates' claims that the '275 patent is unenforceable and to Amgen's claims that it owes no royalties to Columbia due to its inequitable conduct and unclean hands. This misconduct is also relevant to Columbia's failure to meet its obligations under the license agreement to refrain from "repressive practices" – a claim alleged by Amgen and Amgen's Affiliates and also by Biogen IDEC Inc., Biogen IDEC MA Inc., Genzyme Corp., ("Biogen Affiliates"),[11] Wyeth and Genetics Institute.[12] Columbia relied upon this claim to transfer these cases to this Court:

> [T]he close similarity between the complaints carries over to allegations relating to Columbia's obligations under a letter agreement with the National Institute [sic] of Health ("NIH") not to engage in "repressive royalty practices." Six Plaintiffs explicitly present claims relying upon these obligations, while the other six Plaintiffs refer to these obligations in their charging allegations. Moreover, every Plaintiff serving discovery upon Columbia has requested the production of documents on this issue . . . .

Columbia's Reply Br. in Supp. of Mot. to Transfer, Jan. 19, 2004, at 5. As explained above, this repressive practices claim survives the Nov. 5, 2004 Order.

Columbia's principal argument against consolidation – that the Court lacks power to do so[13] – is not correct. Consolidation under Rule 42 is not limited to consolidations "for trial" but also encompasses consolidation "to avoid unnecessary costs and delay," including consolidation of

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[11] *See* Amended Complaint in Civil Action No. 04-CV-12009, Dec. 15, 2004 at ¶ 82, Appendix D hereto. *See also* Amended Complaint of Biogen, Inc., Aug. 31, 2003 at ¶ 15, Appendix E hereto.

[12] *See* their Proposed Amended and Supplemental Complaint, Dec. 6, 2004 at ¶¶ 120-126, Appendix F hereto.

[13] *See* Columbia's opposition to motion to consolidate, at 1 ("[t]his Court does not have the authority to grant Amgen's motion").

pretrial proceedings. *See, e.g., Fritsch v. Dist. Council No. 9*, 335 F. Supp. 854 (S.D.N.Y. 1971) (consolidating for pretrial purposes pursuant to Rule 42(a)); *Robbins v. Pepsi-Cola Metro. Bottling Co.*, 1985 U.S. Dist. LEXIS 12279 (N.D. Ill. 1985) at *7 n.4 (stating that "Rule 42(a) allows consolidation of trial or pretrial proceedings, or both" and that "[c]onsolidation is permitted as a matter of convenience and economy in administration"); *see also In re Paris Air Crash of March 3, 1974*, 69 F.R.D. 310 (C.D. Cal. 1975) (pursuant to Rule 42, ordering consolidation of discovery of certain issues in 12 originally-filed actions and dozens of MDL-transferred cases, and noting that Fed. R. Civ. P. 1 provides that the Federal Rules of Civil Procedure "shall be construed . . . to secure the just, speedy, and inexpensive determination of every action").[14]

The authority cited by Columbia does not prohibit consolidation here. The Court in *In re Tobacco/Governmental Health Care Costs Litig.*, 76 F. Supp. 2d 5, 8 (D.D.C. 1999), recognized its authority to reassign and *consolidate* tag-along cases filed in the transferee district with MDL cases for pretrial proceedings. In *In re Penn Cent. Commercial Paper Litig.*, 62 F.R.D. 341, 344 (S.D.N.Y. 1974), relied upon by Columbia, the court ruled that it lacked authority, over objection, to consolidate MDL-transferred cases *for trial*. However, in that case the two actions *had been consolidated* for pretrial, pretrial proceedings had been completed, and the court was simply recognizing that the case that had been transferred under § 1407 must be remanded for trial.

Columbia erroneously asserts that the Court lacks power to consolidate these MDL proceedings with the Amgen Affiliates' action, because Columbia may later invoke 28 U.S.C. § 1407 to have the original Amgen action transferred back to California for trial. Columbia's concern is not a legitimate basis to deny consolidation. To the extent Columbia retains the right to have the

[14] For further discussion of the reasons supporting Amgen's motion to consolidate, please see its opening and reply memoranda on that motion, attached as Appendices G and H.

original *Amgen* action transferred back to California,[15] consolidation now would not preclude its exercise of that right.

IV. AMGEN'S CASE SHOULD NOT BE REMANDED

At Columbia's request, the JPML ordered these cases transferred to this Court because of the overlap of facts and issues. The Panel decided that placing these cases in one court would "promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a); *see also In re Library Editions of Children's Books*, 299 F. Supp. 1139, 1141 (J.P.M.L. 1969) ("The objective of the legislation is to provide centralized management under court supervision of pretrial proceedings of multidistrict litigation to assure the 'just and efficient conduct' of such actions"). As discussed in detail below, remand at this time would frustrate the just and efficient conduct of the remaining cases.

Moreover, "[r]emand . . . prior to the completion of . . . pretrial proceedings [occurs] only upon a showing of good cause." *In re S. Cent. States Bakery Prod. Antitrust Litig.*, 462 F. Supp. 388, 390 (J.P.M.L. 1978). One court recently summarized the burden and standard that must be met to show that remand is warranted:

> "[A] party seeking remand to the transferor court has the burden of establishing that such remand is warranted." *In re Integrated Resources, Inc. Real Estate Ltd. Partnerships Securities Litigation*, 851 F. Supp. 556, 562 (S.D.N.Y. 1994) . . . . The transferee court, in considering whether to make a suggestion of remand, should be guided by the same standards for remand used by [the] Panel. *In re Bridgestone/Firestone, Inc.*, 128 F. Supp. 2d 1196, 1197 (S.D. Ind. 2001). "The exercise of that discretion generally turns on the question of whether the case will

[15] Columbia has repeatedly argued, and still does, that it wanted "to consolidate all actions in a single district where there would be one trial." Columbia Memo. in Supp. of Motion to Dismiss, *Biogen Idec Inc. v. Trustees of Columbia*, Action No. 04-CV-12009 MLW, Jan. 14, 2005, Appendix I hereto, at 4. It is not necessary for the Court at this time to decide whether Columbia retains rights now to reverse field and demand remand for trial. That can be addressed following pretrial. In fact, even when the Court might ultimately have to decide whether to remand for *trial*, the Court may, pursuant to 28 U.S.C. § 1407, have the option to exercise its discretion to conduct a consolidated *trial*. There is currently pending in Congress a bill that, if signed into law, would amend 28 U.S.C. § 1407 to allow for just such a consolidated *trial*. *See* H.R. 1038, 109th Cong. 1st Sess., attached hereto as Exhibit 5 (the bill was passed by the House of Representatives on April 19, 2005 and has been referred to the Senate Committee for the Judiciary).

> benefit from further coordinated proceedings as part of the MDL." *Id.* (citing *In re Air Crash Disaster*, 461 F. Supp. 671, 672-73 (J.P.M.L. 1978)). Remand is inappropriate when continued consolidation will "eliminate duplicative discovery, prevent inconsistent pretrial rulings, and conserve the resources of the parties, their counsel and the judiciary." *In re Heritage Bonds Litigation*, 217 F. Supp. 2d 1369, 1370 (J.P.M.L. 2002).

In re Nat'l Cent. Fin. Enter., Inc. Fin. Invest. Litig., 2004 WL 882456 (S.D. Ohio 2004) at *2 (denying motion to suggest remand of differently configured Florida actions, noting that neither a complete identity nor "'even [a] majority of common factual issues'" is required).

Columbia has failed to show the requisite good cause to remand and that the cases will not benefit from further coordinated proceedings. On the contrary, continued coordination here is even more proper than when Columbia forced it to begin, because this Court has become very familiar with these cases. To remand now will squander the time and effort which this Court invested in analyzing the subject matter of the Axel patents at issue and Columbia's conduct relating to obtaining those patents. Those issues remain, for at least pretrial management, in common both to Amgen's defenses to Columbia's royalty counterclaims (which Columbia admits are still at issue), as well as to remaining claims of the various plaintiffs, both under the patent laws (*e.g.*, Amgen Affiliates' First, Second and Third Claims, Biogen Affiliates' Counts IV-VI and Amgen's Third Claim as amended) and other theories based, *inter alia*, on Columbia's licensing and patent prosecution misconduct (*e.g.*, Amgen's First and Seventh Claims, Biogen Affiliate's First and Second Claims, Genentech's Fifth Claim, and Wyeth and Affiliate's proposed Twelfth through Fifteenth Claims).

Attached as Exhibit 6 is an amended version of the Table filed February 3, 2005 identifying a number of the common issues among the plaintiffs' actions still pending in this Court. As noted in that table, fact allegations pleaded in the remaining and proposed amended claims of Amgen, the Amgen Affiliates, Biogen Inc. ("Biogen") and its affiliates, Wyeth and its affiliate, and Genentech include many overlapping alleged facts, including the misconduct of Columbia in prosecution of the Axel patents dating back to the early 1980's. As detailed in that Table, these facts are pleaded in

and relevant to at least the contract claims of Amgen (First and Seventh Claims of its SAC), the patent claims of Amgen Affiliates (Action No. 04-12626 MLW), the declaratory relief claim of Biogen (Count I of the Amended Complaint in Action No. 03-CV-11329), the contract claims of Biogen Affiliates (Count II of the Amended Complaint in Action No. 04-CV-12009 MLW), the patent claims of Biogen Affiliates (Counts IV to VII of that action), the contract claims of Wyeth and Affiliate (*e.g.*, the Twelfth Claim in its Proposed Amended Complaint), and the contract claims of Genentech (Fifth Claim in the Complaint in Action No. C-04-1910).

The cases will continue to benefit from consolidation of the necessary discovery by each plaintiff of Columbia's misconduct in the prosecution of the prior expired Axel patents, which will entail the plaintiffs requesting production of, *inter alia*, Columbia's Axel patent prosecution files, and the plaintiffs deposing the named inventors and the attorneys who handled the patent prosecution for the Axel patents, among others. In addition, the validity and enforceability of the '275 patent remain at issue in the patent and "repressive practices" claims of the Amgen Affiliates (Second and Sixth Claims) and Biogen Affiliates (Counts II(B), IV and VI) filed in this Court. And, the Affiliates' '275 patent claims involve facts in common with the inequitable conduct and unclean hand allegations underlying the claims in both Amgen's SAC and proposed TAC.

Similarly, consolidation of pretrial proceedings will conserve resources, avoid inconsistent rulings, and prevent duplicative discovery of common fact issues relating to Columbia's wrongful termination of license agreements, Columbia's failure to comply with the license condition of refraining from repressive practices, Columbia's failure to follow the most favored licensee clauses, and whether plaintiffs overpaid or owe royalties under virtually identical license agreements. For example, Amgen's surviving First Claim, Genentech's surviving Fifth Claim for Breach of Contract, and Wyeth's amended Twelfth Claim allege that each of the plaintiffs owes no royalties under its license agreement with Columbia. Amgen SAC at ¶¶ 60-63; Complaint in *Genentech, Inc. v. Trustees of Columbia Univ.*, Case No. 04-1910 1:04-CV-11546 (MLW) at ¶¶ 45-47; 72-76, attached

as Appendix N; Wyeth's Proposed Amended Complaint at ¶¶ 91-96 (Appendix F, hereto). Amgen seeks a declaration that it owes no royalties for products sold after August 16, 2000, *see* Amgen SAC at ¶¶ 59-63, and has further alleged that it overpaid royalties on Enbrel®, Amgen TAC at ¶ 78. Wyeth similarly alleges that it overpaid royalties on its ReFacto® products, Wyeth Proposed Amended Complaint at ¶ 146, while Genentech alleges that Columbia wrongfully terminated its license and contests Columbia's assertion that Genentech allegedly failed to allow an audit of its books and records in accordance with the terms of the license agreement, *see* Genentech Complaint at ¶ 45 (quoting termination letter from Columbia). Resolution of each of these claims will require analysis of analogous "licensed product" provisions in the license agreements, in order to determine whether royalties were overpaid on products falling outside of the license and to analyze Columbia's allegations that additional accounting or royalty payments may be owed. Requiring three different courts to perform this analysis would not be a just and efficient use of judicial resources.

As another example, both Amgen and Biogen Affiliates seek to recover royalties mistakenly overpaid to Columbia, because Columbia breached, *inter alia*, Section 3(j) of the respective license agreement by failing to disclose the more favorable royalty rate Columbia granted to Genetics Institute. *See* TAC at ¶ 79; Biogen Affiliates Amended Complaint at ¶¶ 83-84; *see also* Exhibit 6 at 4. Because Columbia failed to disclose the more favorable royalty provision of, at least, its license agreement with Genetics Institute to both Amgen and Biogen Affiliates, Amgen and Biogen Affiliates will likely seek similar facts in discovery, including, for example, information relating to Columbia's concealment of the more favorable royalty rate it provided to Genetics Institute, documents relating to the royalty rates Columbia granted to other licensees and testimony from those individuals associated with negotiating the terms of Columbia's license agreements. Furthermore, if these cases were remanded, judicial economy would be wasted interpreting the nearly identical contract language of section 3(j) that exists in all three license agreements. *See* Amgen License

Agreement, Exhibit 2; Genzyme License Agreement, attached hereto as Exhibit 7; Biogen License Agreement, attached hereto as Exhibit 8.

In addition, as part of Amgen's Seventh Claim for Relief, Amgen has pled that Columbia, by failing "to refrain from repressive practices, in derogation of Plaintiffs' rights under the License Agreement," has not satisfied a condition of its license agreement with Amgen. *See* SAC at ¶¶ 21, 89; TAC at ¶¶ 108-111; *see also* Exhibit 6 at 3. Likewise, Biogen Affiliates' Amended Complaint and Wyeth's Proposed Amended and Supplemental Complaint contain nearly identical allegations, a consequence of which will be parallel discovery. *See* Wyeth's Proposed Amended Complaint at ¶¶ 21-23, 120-126**;** Biogen Affiliates' Amended Complaint at ¶¶ 31-32, 82; *see also* Exhibit 6 at 3. Accordingly, not only would a remand of the Amgen case cause two different courts to undertake and oversee analogous discovery, it would result in Columbia's production of similar, if not identical, witnesses and documents in three different cases—a result against which Columbia zealously argued in obtaining consolidation of these actions.

When Columbia sought transfer of Amgen's action to the Northern District of California, and again when Columbia successfully sought transfer of these cases by the Judicial Panel on Multidistrict Litigation, Columbia argued that separate "complex and time-consuming" discovery of the overlapping fact issues in these cases would be inefficient, that separate litigation would require "the same witnesses" to testify on multiple occasions "for the same issues in each of the lawsuits" because "witnesses will face the unreasonable burden of giving the exact same testimony on multiple occasions." Columbia Memo. of P. & A. in Supp. of Mot. to Transfer, Oct. 27, 2003, at 7, attached hereto as Appendix J; Columbia University's Br. in Supp. of Mot. to Transfer under 28 U.S.C. § 1407, Nov. 25, 2003, at 1, 7-8, attached hereto as Appendix K. That burden has not been alleviated by the Nov. 5, 2004 Order. All of the remaining parties will undoubtedly depose many of the same witnesses, such as the named inventors, John White and others involved in Columbia's alleged prosecution and licensing misconduct, witnesses involved in the development of the Axel patent and

'636 patent technologies, Columbia officials involved in the administration of the NIH grant which funded the Axel patent technology, and witnesses relevant to Genetic Institute's sweetheart deal. For all of the reasons previously articulated by Columbia, pre-trial proceedings relating to issues that remain in Amgen's case should be conducted before this Court.

These overlapping facts, which supported Columbia's arguments for MDL treatment in the first instance, remain pleaded and remain pertinent in the cases for pretrial treatment on a consolidated basis in this Court.[16] To remand now would frustrate rather than promote the "just and efficient" conduct of these actions as ordered by the JPML.

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Respectfully submitted,

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[16] For further discussion of the related nature of the cases, please see the Amgen Affiliates' Opposition to the Motion to Dismiss (Appendix L hereto) at 5-6, and their Surreply (Appendix M hereto).